

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicant: Rajinder Singh et al.  
Title: METHODS OF TREATING OR  
PREVENTING AUTOIMMUNE  
DISEASES WITH 2,4-  
PYRIMIDINEDIAMINE  
COMPOUNDS  
Appl. No.: 10/631,029  
Filing Date: 7/29/2003  
Examiner: Raymond J. Henley, III  
Art Unit: 1614  
Confirmation Number: 3056

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to

antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

All references except F1, F2, F4, F5, F10, D1, D42-D44, D49-D51, D53, D56, D58, D61-D65, and D67-D70, are in English.

The English language abstracts of references F1 and F2 are available and attached to the original foreign language Patents. The structural depictions provided therein are readily understood.

Reference F4 was cited in the International Search Report for related Application No. PCT/US03/03022. Only the English language abstract is provided.

Reference F5 has no readily available English language equivalent, but structural depictions provided therein are readily understood.

Reference F10 is provided as a non-English language Patent. An English language equivalent has been published and is US Patent Publication No. 2004/0102630 (Reference P10).

References D5-D41 correspond to chemical abstracts cited by the Russian Patent Office in related Russian Application No. 2004126431, which corresponds to US Application No. 10/355,543.

References D43 and D69 are in the Russian language. Since these articles are being submitted for compounds identified in the chemical abstracts, and structure of those compounds are being provided concurrently (D5-D41), translations are not required.

References D1, D42-D44, D49-D51, D53, D61-D65, D67-D70 were cited by the Russian Patent Office during examination in related Russian Application No. 2004126431. English

language equivalents are not readily available, but the structural depictions are readily understood.

References D56 and D58 were cited by the US Patent and Trademark Office during examination of related US Application No. 10/991,684. English language equivalents are not readily available, but the structural depictions provided therein are readily understood.

For the documents where an English language translation of the foreign-language documents is not readily available, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Fees in the amount of \$180.00 in accordance with 37 CFR §1.17(p) to cover the fee associated with an information disclosure statement under 37 CFR §1.97(c) are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 6 June 2007

By Karen E. Flick

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Karen E. Flick  
Attorney for Applicant  
Registration No. 44,111

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Substitute for form 1449/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			<b>Application Number</b>	10/631,029
			<b>Filing Date</b>	7/29/2003
			<b>First Named Inventor</b>	Rajinder SINGH
			<b>Art Unit</b>	1614
			<b>Examiner Name</b>	Raymond J. Henley, III
(use as many sheets as necessary)			<b>Attorney Docket Number</b>	064311-1602
Sheet	1	of	6	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	P1	3,320,256	5/1/1967	Duschinsky, et al.	
	P2	4,968,781	11/1/1990	Seitz, et al.	
	P3	6,093,716	7/25/2000	Davis, et al.	
	P4	6,586,594	7/1/2003	Butters, et al.	
	P5	6,939,874 B1	9/6/2005	Harmange, et al.	
	P6	2003-0134838 A1	7/17/2003	Bornemann, et al.	
	P7	2003-0171359 A1	9/11/2003	Dahmann, et al.	
	P8	2004-0063737 A1	4/1/2004	Lucking, et al.	
	P9	2004-0097504 A1	5/20/2004	Ebethiel et al.	
	P10	2004-0102630 A1	5/27/2004	Brumby, et al.	
	P11	2004-0147507 A1	7/29/2004	Ledeboer et al.	
	P12	2005-0054732 A1	3/10/2005	Meguro, et al.	
	P13	2005-0272753 A1	12/8/2005	Nagashima, et al.	
	P14	2006-0270694	11/30/2006	Wong	
	P15	2007-0004626	1/4/2007	Masuda et al.	
	P16	2007-0060603 A1	3/15/2007	Singh, et al.	

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Application Document	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number-Kind Code <sup>2</sup> (if known)			
	U1	11/539013	10/5/2006	Singh et al.	
	U2	11/539018	10/5/2006	Singh et al.	
	U3	11/539142	10/5/2006	Singh et al.	
	U4	11/539147	10/5/2006	Singh et al.	
	U5	11/539520	10/6/2006	Singh et al.	
	U6	11/555222	10/31/2006	Payan	

Examiner Signature	Date Considered
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**Art Unit** 1614  
**Examiner Name** Raymond J. Henley, III  
**Attorney Docket Number** 064311-1602

Sheet 2 of 6

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code* Number* Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	F1	EP 0 139 613	8/23/1984	Ciba-Geigy AG		No
	F2	EP 0 248 348	5/1/1987	Glencke et al.		No
	F3	EP 1 056 742 B1	12/6/2000	Tularik Inc.		Yes
	F4	JP 03/127790 A	5/20/1991	Morishita Pharm., Co., Ltd.		Yes
	F5	SU 1499883 A1	10/23/1991	NII Farmakologii Amn SSSR		No
	F6	WO 01/23362 A2	4/5/2001	Knoll AG		
	F7	WO 01/30782	5/2/2001	Syngenta Participation AG		
	F8	WO 02/016306	2/27/2002	Janssen Pharmaceutica N.V.		
	F9	WO 02/068409	9/1/2002	Claiborne et al.		
	F10	WO 02/096888 A1	12/5/2002	Schering AG		No
	F11	WO 03/055489 A1	7/10/2003	Bayer Corp.		
	F12	WO 04/041814 A1	5/21/2004	Vertex Pharmaceuticals, Inc.		
	F13	WO 2004/014384	2/19/2004	Rigel Pharmaceuticals, Inc.		
	F14	WO 2005/016893 A2	2/24/2005	Rigel Pharmaceuticals, Inc.		
	F15	WO 2005/027848 A2	3/31/2005	Barnes Jewish Hospital		

**NON PATENT LITERATURE DOCUMENTS**

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	D1	ARUTYUNYAN et al. 1970, "Reaction of uracils with phosphoric acid amides" <i>Izvestiya Akademii Nauk SSSR, Seriya Khimicheskaya</i> 4:904-909	No
	D2	BANKS 1944, "Arylaminoheterocycles. II. Arylaminoipyrimidines" <i>Journal of American Chemical Society</i> 66:1131	

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**Examiner Name** Raymond J. Henley, III  
**Attorney Docket Number** 064311-1602

Sheet 3 of 6

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	D3	BRITKOVA et al. 1966, "Derivatives of Orotic Acid and its Analogs IV, Synthesis and Properties of Amino Acid Derivatives of the Lactone of 5-(Hydroxymethyl)pyrimidine-4-carboxylic Acid" <i>Khimiya Geterosiklichesikh Soedinenii</i> 2(5):783-790 (as translated in <i>Chemistry of Heterocyclic Compounds</i> , 1968 The Faraday Press, pgs. 606-611)	
	D4	BROWN 1954, "Improved Syntheses in the Pyrimidine Series. III. 5-Amino-4-(methylamino)pyrimidine" <i>J. Appl. Chem.</i> 4:72-75	
	D5	Chemical Abstracts 64:27547, compound 5177-26-4, 1954	
	D6	Chemical Abstracts 66:2531, compound 13150-23-7P, 1966	
	D7	Chemical Abstracts 67:64344, compound 15783-61-6P, 1996	
	D8	Chemical Abstracts 67:64344, compound 15783-79-6P, 1996	
	D9	Chemical Abstracts 71:81300, compound 19144-75-3P, 1967	
	D10	Chemical Abstracts 71:81300, compound 19144-76-4P, 1967	
	D11	Chemical Abstracts 72:111409, compound 26857-80-7P, 1969	
	D12	Chemical Abstracts 73:35322, compound 28458-89-1, 1944	
	D13	Chemical Abstracts 74:141685, compound 31796-90-4, 1970	
	D14	Chemical Abstracts 74:141685, compound 31796-91-5, 1970	
	D15	Chemical Abstracts 74:141685, compound 31796-99-3, 1970	
	D16	Chemical Abstracts 74:141685, compound 31797-00-9, 1970	
	D17	Chemical Abstracts 74:141685, compound 31797-01-0, 1970	
	D18	Chemical Abstracts 74:141685, compound 31797-09-8, 1970	
	D19	Chemical Abstracts 74:3577, compound 29935-92-0, 1970	
	D20	Chemical Abstracts 74:3577, compound 29935-93-1, 1970	
	D21	Chemical Abstracts 74:3577, compound 29935-94-2, 1970	
	D22	Chemical Abstracts 74:3577, compound 29935-98-6, 1970	
	D23	Chemical Abstracts 74:3577, compound 29935-99-7, 1970	
	D24	Chemical Abstracts 74:51826, compound 31414-49-0, 1970	
	D25	Chemical Abstracts 74:51826, compound 31414-50-3, 1970	
	D26	Chemical Abstracts 74:3577, compound 29935-96-4, 1970	
	D27	Chemical Abstracts 74:3577, compound 29935-97-5, 1970	
	D28	Chemical Abstracts 75:5843, compound 30953-40-3P, 1970	
	D29	Chemical Abstracts 75:5843, compound 32090-58-7P, 1970	
	D30	Chemical Abstracts 75:5843, compound 32090-59-8P, 1971	
	D31	Chemical Abstracts 78:97592, compound 40423-75-4, 1971	

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		<b>Art Unit</b>	1614
		<b>Examiner Name</b>	Raymond J. Henley, III
		<b>Attorney Docket Number</b>	064311-1602
Sheet	4	of	6

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	D32	Chemical Abstracts 78:97592, compound 40423-76-5P, 1971		
	D33	Chemical Abstracts 78:97592, compound 40423-83-4P, 1971		
	D34	Chemical Abstracts 78:97592, compound 40423-84-5P, 1971		
	D35	Chemical Abstracts 78:97592, compound 40505-53-1P, 1971		
	D36	Chemical Abstracts 78:97592, compound 40864-28-6P, 1971		
	D37	Chemical Abstracts 79:39197, compound 29935-97-5, 1970		
	D38	Chemical Abstracts 83:126278, compound 40423-75-4, 1971		
	D39	Chemical Abstracts 86:89050, compound 61763-95-9, 1976		
	D40	Chemical Abstracts 86:89050, compound 61798-30-9, 1976		
	D41	Chemical Abstracts 88:151697, compound 66229-55-8P, 1978		
	D42	CHERKASOV et al. 1970, "Aminolysis of 2,4-dichloro-5-nitro-6-aminopyrimidine" <i>Ukrainskii Khimicheskii Zhurnal (Russian Edition)</i> 36(7):694-696	No	
	D43	CHKHIKVADZE et al. 1967, "Preparation of 7-Substituted 5,6-Dihydropyrido[2,3-d]pyrimidines or its derivatives" <i>Khimiya-Farmatsevticheskii Zhurnal</i> 2:5-12	No	
	D44	CHKHIKVADZE et al. 1969, "5-Substituted pyrimidines. II. Synthesis of 5,6-dihydropyrido[2,3-d]pyrimidines(5,7-diazaindolines)" <i>Khimiya Geterotsiklicheskih Soedinenii</i> 1:138-144	No	
	D45	COOK et al. 1978, "Fluorinated Pyrimidine Nucleosides. 2 reaction of 2,2'-anhydro-1-b-D-Arabinofuranosyl-2-fluorocytosine Hydrochloride with Nitrogen and Sulfur Nucleophiles" <i>J. Org. Chem.</i> 43(21):4200-4206		
	D46	EL-KERDAWY et al. 1986, "2,4-Bis(Substituted)-5-Nitropyrimidines of Expected Diuretic Action" <i>Egypt J. Chem.</i> 29(2):247-251		
	D47	GHOSH & MUKHEJEE 1967, "2,4-Bis(arylamino)-5-methylpyrimidines as Antimicrobial Agents" <i>J. Med. Chem.</i> 10:974-975		
	D48	GHOSH 1981, "2,4-Bis(Arylamino)-6-Methyl Pyrimidines as Antimicrobial Agents" <i>J. Indian Chem. Soc.</i> 58:512-513		
	D49	GRIGOREVA et al. 1979, <i>Chemico-Pharm. J.</i> 13(3):5-10	No	
	D50	GRIGOREVA et al. 1980, <i>Chemico-Pharm. J.</i> 14(8):7-11	No	
	D51	KOKORIN et al. 1976, "EPR study of the conformation of triazine series nitroxyl biradicals" <i>Izvestiya Akademii Nauk SSSR, Seriya Khimicheskaya</i> 9:1994-1999	No	
	D52	LUDOVICI et al. 2001, "Evolution of Anti-HIV Drug Candidates. Part 3: Diarylpyrimidine (DAPY) Analogues" <i>Bioorg. Med. Chem. Lett.</i> 11:2235-2239		
	D53	MAMAEV & SEDOVA 1965, "Pyrimidines. III. Dehydrogenation of 4-phenylbenzo[h]quinazoline derivatives" <i>Khimiya Geterotsiklicheskih Soedinenii</i> 4:608-615	No	

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	D54	MANESIOTIS et al. 2005, "Improved Imide Receptors by Imprinting Using Pyrimidine-Based Fluorescent Reporter Monomers" <i>J. Org. Chem.</i> <b>70</b> :2729-2738		
	D55	MASHKOVSKY 1993, <i>Meditina</i> 1.8		Yes
	D56	MOKHORT 1970, "Search for Non-steroid Antiinflammatory Substances among Heterocyclic Anthranilic Acid Derivatives" <i>Farmatsevtichnii Zhurnal (Kiev)</i> <b>25</b> (4):76		No
	D57	PAEGLE et al. 1971, "Synthesis and Properties of N-(2-chloro-5-fluoro-4-pyrimidyl)- and N-(2-thiylthio-5-fluoro-4-pyrimidyl)amino Acids" <i>Khimiya Geterotsiklicheskih Soedinenii</i> <b>7</b> (2):258-261		Yes
	D58	POLIS 1970, "Mechanism of C-N Bond Breaking in Substituted Amines" <i>Khimiya Geterotsiklicheskih Soedinenii</i> <b>4</b> (571)		No
	D59	POPOVA et al. 1996A, "Study of Reactions of 2,4,6-Trifluoropyrimidines and 2- and 4-Aminodifluoropyrimidines with Ethylamine" <i>J. Org. Chem.</i> <b>32</b> (5):749-755, as translated from <i>Zhurnal Organicheskoi Khimii</i> <b>32</b> (5):781-787		Yes
	D60	POPOVA et al. 1996B, "Synthesis and Properties of 2- and 4-Aminodifluoropyrimidines" <i>J. Org. Chem.</i> <b>32</b> (9):1424-1429, as translated from <i>Zhurnal Organicheskoi Khimii</i> <b>32</b> (9):1418-1423		Yes
	D61	PORTNYAGINA & DANILENKO 1971, "Guanidine derivatives of pyrimidine" <i>Khimiko-Farmatsevticheskii Zhurnal</i> <b>5</b> (4):15-17		No
	D62	PROTSENKO et al. 1966, "Derivatives of pyrimidine. III. Bis(ethylenimino)pyrimidines" <i>Ukrainskii Khimicheskii Zhurnal (Russian Edition)</i> <b>32</b> (8):867-871		No
	D63	PROTSENKO et al. 1970, "Reaction of ethyleniminopyrimidines with hydrogen chloride" <i>Ukrainskii Khimicheskii Zhurnal (Russian Edition)</i> <b>36</b> (10):1043-1047		No
	D64	RYABUKHA & MOKHORT 1970, "Relation between structure and pharmacological action in guanidino derivatives of pyrimidine" <i>Farmakologiya i Toksikologiya (Kiev)</i> <b>5</b> :64-67		No
	D65	SMIRNOV et al. 1969, "Products of the reaction of cyanuric trichloride with diiminoisindoline" <i>Izvestiya Vysshikh Uchebnykh Zavedenii, Khimiya i Khimicheskaya Tekhnologiya</i> <b>12</b> (10):1420-1423		No
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	D67	TRETYAKOVA et al. 1972, "Physiological activity of some amino- and chloropyrimidines" <i>Fiziologicheski Aktivnye Veshchestva</i> <b>4</b> :93-95		No
	D68	TRETYAKOVA et al. 1980, <i>Phys. Active Substances</i> <b>12</b> :63-67		No

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			<b>Application Number</b>	10/631,029
			<b>Filing Date</b>	7/29/2003
			<b>First Named Inventor</b>	Rajinder SINGH
			<b>Art Unit</b>	1614
			<b>Examiner Name</b>	Raymond J. Henley, III
Date Submitted: 6 June 2007			<b>Attorney Docket Number</b>	064311-1602
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	D69	TRINUS et al. 1970, "Correlation Between the Chemical Structure and Pharmacological Activity of Nitrogen-Containing Heterocyclic Guanidine Derivatives" <i>Farmatsevtichini Zhurnal (Kiev)</i> 25(6):66-68	No
	D70	ZAGULYAEVA et al. 1978, "Relative reactivity of chlorine atoms in 2,4-dichloropyrimidine in reactions with ammonia and amines in isooctane and ethanol" <i>Zhurnal Organicheskoi</i> 14(2):409-13	No

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